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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/402,131	12/08/1999	VALERIE CHEYNET-SAUVION	104458	5581

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EXAMINER

SISSON, BRADLEY L

ART UNIT PAPER NUMBER

1634

DATE MAILED: 07/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/402,131

Applicant(s)

CHEYNET-SAUVION ET AL.

Examiner

Bradley L. Sisson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-41,43-47 and 69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-41,43-47 and 69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 26 March 2003 has been entered.

Oath/Declaration

2. The following is a quotation of the appropriate paragraph of 37 CFR 1.67(b) that form the basis for the objection under this section made in this Office action:

A supplemental oath or declaration meeting the requirements of § 1.63 must be filed when a claim is presented for matter originally shown or described but not substantially embraced in the statement of invention or claims originally presented or when an oath or declaration submitted in accordance with § 1.53(f) after the filing of the specification and any required drawings specifically and improperly refers to an amendment which includes new matter. No new matter may be introduced into a nonprovisional application after its filing date even if a supplemental oath or declaration is filed. In proper situations, the oath or declaration here required may be made on information and belief by an applicant other than the inventor.

As a result of amendment(s) to the claim(s), the pending claims no longer substantially embrace the invention as set forth in the statement of the invention and/or in the original claims.

Accordingly, applicant is required to file a supplemental oath or declaration in response to this Office action.

Specification

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Objections

4. Claims 40, 41 and 43-47 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Sole independent claim 35 stipulates that the method is to be conducted "in the absence of deoxyribonucleoside triphosphates" yet the method of claims 40 and 41 seemingly broaden the claim's scope to where DNA is included. Additionally, claim 35 stipulates that the RNA polymerase "is a T7-like phage RNA polymerase." Claims 43-47 seemingly broaden the claim's scope to include other polymerases.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 35-41, 43-47, and 69 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the

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relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Attention is directed to the decision of *Vas-Cath Inc. v. Mahurkar* 19 USPQ2d 1111 (CAFC, 1991):

This court in *Wilder* (and the CCPA before it) clearly recognized, and we hereby reaffirm, that 35 USC 112, first paragraph, requires a "written description of the invention" which is separate and distinct from the enablement requirement. The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the "applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the "written description" inquiry, *whatever is now claimed*.

For purposes of examination, claim 35 has been interpreted as encompassing virtually any polymerase and any promoter. A review of the disclosure finds that the promoter must be double stranded DNA. In support of this position, attention is directed to the following passage from page 2 of the disclosure:

protein polymerase...
It has now been discovered that some known DNA-dependent RNA polymerases are capable of transcribing a single-stranded RNA in the presence of a double-stranded DNA promoter. Furthermore, some of these

The method of claim 35 places no limitation on minimum sizes of the various segments of the nucleotide strands. A review of the disclosure, fails to find adequate support for such breadth of scope. As set forth at page 7 of the disclosure:

The first segment contains a sufficient number of nucleotides to be able, in the hybridized state, to play the role of a promoter for an RNA polymerase. According to a specific embodiment, the first segment contains at least 9 nucleotides. (Emphasis added)

Page 5 of the specification teaches in detail how highly conserved the promoter of T7 is; yet the claims encompass alternative promoter sequences. The specification fails to set forth in sufficient detail other such embodiments so to reasonably suggest that applicant was in

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possession of a genus of suitable promoters. Seemingly applicant is trusting in certain embodiments being obvious to the skilled artisan. Obviousness, however, cannot be relied upon in satisfying the written description requirement of 35 USC 112, first paragraph. In support of this position, attention is directed to the decision in *University of California v. Eli Lilly and Co.* (Fed. Cir. 1997) 43 USPQ2d at 1405, citing *Lockwood v. American Airlines Inc.* (Fed. Cir. 1997) 41 USPQ2d at 1966:

Recently, we held that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention.

6. Claims 35-41, 43-47, and 69 place no limitation on the length of the fourth segment.

Page 8 of the disclosure, however, states that the fourth segment is to have a length of from 1 to 18 nucleotides. In view of such explicit guidance, the specification has not been found to support claims where the length of the fourth segment exceeds the contemplated range.

7. In view of the above reasoning, the specification has not been found to provide adequate written support for the full scope of the claimed invention. Applicant is urged to consider narrowing the claims' scope such that it more closely parallels the invention set forth in the originally-filed disclosure.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 35-41, 43-47, and 69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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10. Claim 35 is indefinite with respect to what constitutes "T7-like phage RNA polymerase."

It is noted with particularity that dependent claim 43, for example, refers to T3 and SP6 RNA polymerases. It is unclear how other polymerases are to fall under the umbrella of T7 RNA polymerase. Claims 36-41, 43-47, and 69, which depend from said claim 35, fail to overcome this issue and are similarly rejected.

11. Claim 35 is indefinite with respect to there being "an absence of deoxyribonucleoside triphosphates" yet claim 46, for example, specifically recites that DNA be present. The presence of DNA speaks to the presence of intact and fragmentary DNA, including nucleotides and nucleosides. Claims 36-41, 43-47, and 69, which depend from said claim 35, fail to overcome this issue and are similarly rejected.

12. Claim 45 is indefinite with respect to what SEQ ID NO. the amino acids are in reference to. Claim 46, which depends from said claim 45, fails to overcome this issue and is similarly rejected.

13. The term "better" in claim 46 is a relative term that renders the claim indefinite. The term "better" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 69 is indefinite with respect to what SEQ ID NO. the defined positions are in reference to.

Conclusion

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.
15. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.
16. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
July 28, 2003